Basis for Staff's Reevaluation of the Adequacy of Exemptions

The primary guidance for the Commission's decisions in establishing (or revising) exemptions from licensing is the 1965 Consumer Product Policy (published March 16, 1965; 30 FR 3462) (the policy). Despite the age of the policy, its content continues to be generally appropriate and consistent with the Commission's current approach to radiation protection and the basic framework for radiation protection recommended by the International Commission on Radiological Protection (ICRP). It incorporates some considerations related to the three basic principles of radiation protection: justification of practice, dose limits, and ALARA, although justification of practice and ALARA are not explicitly noted. The policy states that, "Approval of a proposed consumer product will depend upon both associated exposures of persons to radiation and the apparent usefulness of the product." Generally, a product is acceptable for use by the general public if it is unlikely to result in doses exceeding a small fraction (a few hundredths) of limits recommended for exposure to radiation from all sources, and the probability of individual doses approaching any of the limits is negligibly small. At the time the policy was written, there was a limit for doses to the general public of 500 mrem/year (5 mSv/year) recommended by various groups, such as the ICRP, National Council on Radiation Protection and Measurements (NCRP), and the Federal Radiation Council (FRC). The revised Part 20 (effective no later than January 1, 1994) established a public dose limit of 100 mrem/year (1 mSv/year)(§ 20.1301) from licensed activities. The recommended dose limit for the public was not explicitly stated in the policy, so it has not been made outdated by the use of specific dose criteria which are no longer applicable, although the value of this small fraction would be lower under current recommendations/limits.

Because the policy has not been revised since 1965, it does not address all factors that need to be considered at this time. One change that has occurred since adoption of the policy is the move away from the concept of radiation worker and the clear separation of occupational dose and public dose now in Part 20. Persons exposed while working at an unlicensed facility are considered to be receiving an occupational dose in accordance with the definition in § 20.1003; thus, these exposures do not need to be within the dose limits in § 20.1301(a) for individual members of the public. However, for consistency in protection of health and safety, an exemption from Part 20 should not be applicable in situations where a worker could receive (under routine conditions) more than 10 % of the occupational limit or 500 mrem/year (5 mSv/year) as there would be no required monitoring of exposures (consistency with § 20.1502). An exemption from licensing (where Parts 19 and 20 do not apply) should not result in untrained workers being likely to receive more than 100 mrem/year (1 mSv/year)(consistency with § 19.12). Exceptions to this may be appropriate based on cost/benefit considerations, because the cost of specific licensees providing training to a larger number of employees based on the 100 mrem/year (1 mSv/year) criterion is different from the total cost of licensing a practice.

Thus, the staff believes that the use of radioactive materials in situations where training or monitoring of workers would not be required, should meet the following conditions: Workers are not routinely expected to receive more than 100 mrem/year (1 mSv/year) from sources exposed to in the course of work (not including exposures received as members of the public). It is possible that even routine, non-accident conditions could occasionally result in an exposure greater than 100 mrem/year (1 mSv/year) (but not greater than 500 mrem/year (5 mSv/year)),

from sources exposed to in the course of work (not including exposures received as members of the public).

For low probability events (accidents), some probability of workers receiving greater than 500 mrem/year (5 mSv/year) is acceptable. Risk should be considered based on both the probability of an event and the maximum likely exposure. The policy includes consideration of potential accident doses and probabilities of occurrence, but does not provide specific guidance on what is acceptable. In looking at the results for the misuse and accident scenarios in the radiological assessment, the staff has considered that the safety criteria in the two class exemptions: §§ 30.19 and 30.20, self-luminous products and gas and aerosol detectors, respectively, are appropriate for judging the acceptability of risks from accidents and misuse for other exemptions as well. These safety criteria are contained in §§ 32.23 and 32.24 for self-luminous products and in §§ 32.27 and 32.28 for gas and aerosol detectors. (The dose criteria are, however, stated in terms of whole body and organ doses in lieu of total effective dose equivalent (TEDE) which is used in Part 20. Thus for consistency, the staff recommendations include revising §§ 32.24 and 32.28 and related sections to state the criteria in terms of TEDE.) Although these safety criteria are for exposures of the general public, the level of risk in the case of low probability events is also considered appropriate for workers at unlicensed facilities, where workers are not trained or monitored. For example, devices generally licensed under § 31.5 are required by § 32.51(a)(2)(iii) to meet the same 15 rem limit in § 32.24 for accidents such as fire and explosion.

Note that although 100 mrem/year (1 mSv/year) is the primary criterion, as it is for public dose, it is appropriate to look at occupational and public doses separately. Workers are enjoying the benefit of having a job, although they should be similarly protected as workers at specifically licensed facilities. For either a member of the public or an untrained worker, doses above 100 mrem/year (1 mSv/year) may be justifiable in some cases based on cost/benefit considerations, e.g., the patient release criterion of 500 mrem (5 mSv) (§ 35.75) and case-by-case determinations allowed by § 20.1301(c).

A goal of NRC regulations is that exposures to the public are unlikely to exceed 100 mrem/year (1 mSv/year) from all practices under NRC jurisdiction (with limited probability of individuals' doses sometimes exceeding this). Thus, there are lower dose limits for individual practices, particularly where the public may be exposed to multiple sources. One of the criteria in the consumer product policy, which addresses only exposures to the general public, is for each exempt practice to result in a small fraction of the public dose limit, because members of the public may be exposed to a number of consumer products. The intent is that resultant exposures of members of the general public from all exempt products are unlikely to be a significant fraction of the permissible dose as they may also be exposed to other sources such as effluent releases from licensees.

Widely distributed items would be expected to contribute to the exposures of large numbers of people and thus there should be a higher degree of assurance that routine doses from individual practices involving such items meet the small fraction of the public dose limit criterion.

While the policy does not refer to the concept of justification, it does include consideration of the degree of benefit or usefulness of a product to the public and indicates that the use of radioactive material in toys, novelties, and adornments may be of marginal benefit. There is an explicit

exclusion in the class exemption for self-luminous products (§ 30.19(c)) of products primarily for "frivolous" purposes and of toys and adornments. Nonetheless, the benefit of a particular product distributed for use under this exemption may be minimal, thus, it has the lowest practice-specific dose criterion of 1 mrem/year (10 μSv/year) from normal use and disposal (safety criteria in §§ 32.23 and 32.24). Applying the concept of justification also minimizes the number of products made available for use by the general public under the exemptions from licensing. This helps to ensure that exposures to the public are unlikely to exceed 100 mrem/year (1 mSv/year) from all practices under NRC control.

Looking at the scenarios in which the critical group (the group of people reasonably expected to receive the greatest exposure from a practice) is occupationally exposed, e.g., welding, it would be reasonable for routine doses to these workers to approach 100 mrem/year (1 mSv/year), if it is unlikely that they are occupationally exposed to other sources. Generally, there are few situations in which the same workers would be expected to be the critical group for multiple practices. However, waste collectors and workers at disposal facilities, i.e., landfills and incinerators, are potentially exposed to all categories of radioactive material allowed to be disposed of without regard to its radioactivity. In order for their cumulative dose from these materials/products to be acceptable, their dose from any individual practice should be quite small. The estimates in NUREG-1717 for disposal workers and for members of the general public from disposal do not suggest that the net effects of uncontrolled disposals are significant. Waste collectors have the highest potential exposures, up to a few mrem/year from a single practice but a small fraction of 1 mrem/year (10 μSv/year) from most.

The policy and this discussion focus on control of individual doses. NUREG-1717 also estimated collective doses. Given the uncertainty in the estimates and the fact that the collective doses are, for the most part, summing very small individual doses, the staff has considered the collective dose estimates only as general indicators of the magnitude of benefit to be achieved by actions that may reduce individual doses. In evaluating the results of the dose assessments in NUREG-1717, particular attention was paid to identifying potential regulatory improvements for exemptions for which either the potential individual doses or the estimated collective doses were relatively high in comparison to others. Both the reduction of maximum potential individual doses and associated impacts in terms of collective doses should be considered in the Regulatory Analyses for rulemakings in this area. Generally speaking, the control of individual doses tends to improve the cost/benefit balance for the practice, as it also reduces the average collective dose per product. The total collective dose also depends on the degree to which a product is used. The larger the number of a product used, the greater the collective dose, but also the greater the benefit, or at least perceived benefit, of a practice to society.